IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2974 1:20-md-02974-LMM
This document relates to: Pauline Rickard	:	CIVIL ACTION NOs.: 1:21-cv-03861-LMM

ORDER

This case is part of a multi-district litigation ("MDL") involving the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The case is now before the Court on Teva's Motion for Summary Judgment of the claims of bellwether plaintiff Pauline Rickard ("Plaintiff"), Dkt. No. [50].[1] Upon due consideration, and with the benefit of oral argument, the Court enters the following Order.

I. LEGAL STANDARD

Rule 56 of the Federal Rules of Civil Procedure provides that "[t]he court shall grant summary judgment if the movant shows that there is no genuine

[1] "Teva" or "Defendant" refers collectively to Defendants Teva Pharmaceuticals USA, Inc.; Teva Women's Health, LLC; and Teva Branded Pharmaceutical Products R&D, Inc. Defendant CooperSurgical, Inc. ("Cooper"), which jointly filed the present motion with Teva, was granted summary judgment of Plaintiff's claims in other Orders. See Dkt. Nos. [116, 137, 138].

dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A factual dispute is genuine if the evidence would allow a reasonable jury to find for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is "material" if it is "a legal element of the claim under the applicable substantive law which might affect the outcome of the case." Allen v. Tyson Foods, Inc., 121 F.3d 642, 646 (11th Cir. 1997).

The moving party bears the initial burden of showing the Court, by reference to materials in the record, that there is no genuine dispute as to any material fact that should be decided at trial. Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1260 (11th Cir. 2004) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)). The moving party's burden is discharged merely by " 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support [an essential element of] the nonmoving party's case." Celotex Corp., 477 U.S. at 325. In determining whether the moving party has met this burden, the district court must view the evidence and all factual inferences in the light most favorable to the party opposing the motion. Johnson v. Clifton, 74 F.3d 1087, 1090 (11th Cir. 1996).

Once the moving party has adequately supported its motion, the non-movant then has the burden of showing that summary judgment is improper by coming forward with specific facts showing a genuine dispute. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). "Where the

record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.' " Id. "The mere existence of a scintilla of evidence" supporting the non-movant's case is insufficient to defeat a motion for summary judgment. Anderson, 477 U.S. at 252. All reasonable doubts, however, are resolved in favor of the non-movant. Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1115 (11th Cir. 1993).

II. BACKGROUND

A. Facts

Paragard is an IUD that is implanted into a patient's uterus by a healthcare provider. It is a T-shaped device that is made of polyethylene milled with barium sulfate and wrapped in copper. It is indicated for intrauterine contraception for up to 10 years. The T-shape is designed to collapse for insertion and removal. It is supposed to be easy for a healthcare practitioner to remove the Paragard by gently pulling on attached threads.

Paragard has been approved and regulated by the FDA since 1984 without any significant design updates. Teva became the owner of the Paragard NDA in December 2008 and held it until the NDA was acquired by Cooper on November 1, 2017.

Plaintiff underwent placement of a Paragard by Richard Chlouber, M.D., in May 2012. At the time Plaintiff had her Paragard placed, there was nothing in the Warnings, Adverse Reactions, or Patient Information section of the label about Paragard breakage, and Plaintiff expected for the removal of her Paragard to be

simple and easy. But when she had her Paragard removed by Niloufer Kero, M.D., in August 2021, the Paragard was broken, and Dr. Kero was not able to remove one arm of the Paragard. Dr. Kero sent Plaintiff for an ultrasound, which revealed that the missing Paragard piece was in Plaintiff's lower uterine cavity. Twelve days after the first attempt to remove the Paragard, Dr. Kero performed a hysteroscopy and dilation and curettage, while Plaintiff was under full anesthesia, to remove the remaining arm.

B. Procedure

Plaintiff asserts twelve claims against Defendants, all under state law: Strict Liability—Design Defect (Count I); Strict Liability—Failure to Warn (Count II); Negligence (Count IV); Negligence—Design Defect (Count V); Negligence—Failure to Warn (Count VI); Fraud & Deceit (Count VII); Fraud by Omission (Count VIII); Negligent Misrepresentation (Count IX); Breach of Express Warranty (Count X); Breach of Implied Warranty (Count XI); Gross Negligence (Count XIII); and Punitive Damages (Count XV).[2] In support of the claims, Plaintiff alleges that by 2010, before her Paragard placement, the label should have—but did not—warn that Paragard could break during routine and non-surgical removal, even without embedment; indicate the frequency of the

[2] Plaintiff also asserted claims of Strict Liability—Manufacturing Defect (Count III); Negligence—Manufacturing Defect (Count V); Violation of Consumer Protection Laws (Count XII); and Unjust Enrichment (Count XIV). She has since agreed to dismiss those claims with prejudice. Dkt. No. [53].

breakages; warn that if Paragard broke, it could cause serious injury, require surgical intervention, or result in loss of reproductive health or fertility; warn of breakage or these injuries in the "Warnings," "Precaution," or "Adverse Reactions" section of the label; or warn of Paragard breakage in the Patient Package Insert. She also alleges that several design defects—the composition of the materials in the Paragard base, the lack of storage controls for the base materials, and the right angles in the Paragard's T-shaped base—caused the Paragard to break and injure her.

Teva and Cooper filed two other motions for summary judgment in addition to the present motion. In Orders on those motions, the Court granted summary judgment in favor of Cooper on the claims Plaintiff asserted against it. See Dkt. Nos. [116, 137, 138]. It also narrowed Plaintiff's claims for design defect to those arising from the use of Dupont 20 rather than Dupont 2005 and the incorporation of up to 24% barium sulfate in the Paragard base materials. Dkt. No. [137]. Teva now seeks summary judgment of Plaintiff's remaining claims. Dkt. No. [50].

III. DISCUSSION

The parties have determined that Florida law applies to all of Plaintiff's claims, except as to Plaintiff's claim for punitive damages, which Teva argues is governed by Florida law, and Plaintiff contends is governed by New York law. Teva argues primarily that the remaining warnings-based claims fail because

Plaintiff cannot establish proximate cause or show that the labeling was inadequate and that the remaining design-defect claims fail because Plaintiff lacks admissible expert testimony connecting an actual design defect to her injuries. Teva also moves for summary judgment of Plaintiff's claims for fraud, breach-of-warranty, gross negligence, and punitive damages on alternative grounds. The Court shall address the arguments in logical order.

A. Warnings-Based Claims

To prove a failure-to-warn claim under Florida law, "the plaintiff must show (1) that the product warning was inadequate; (2) that the inadequacy proximately caused her injury; and (3) that she in fact suffered an injury from using the product." Salinero v. Johnson & Johnson, 995 F.3d 959, 964 (11th Cir. 2021) (cleaned up); accord Cates v. Zeltiq Aesthetics, Inc., 73 F.4th 1342, 1347 (11th Cir. 2023); Hoffmann-La Roche, Inc. v. Mason, 27 So. 3d 75, 77 (Fla. Ct. App. 2009). Teva argues that Plaintiff's failure-to-warn claims fail because the learned-intermediary doctrine defeats proximate cause and because Plaintiff cannot prove that the label was inadequate. Plaintiff, in turn, contends that the learned-intermediary doctrine does not apply and that even if it did, she has demonstrated that the Paragard label inadequately warned of breakage, whether the duty to warn ran to her or to her implanting physician.

1. Learned-Intermediary Doctrine

The Court held in a previous Order that the learned-intermediary doctrine applies in this case. Dkt. No. [138] at 6-8. Florida's learned-intermediary doctrine

establishes that a manufacturer of a product, particularly a prescription drug or other specialized product, can fulfill its duty to warn end users of potential dangers by adequately warning a "learned intermediary," such as a prescribing physician. Mason, 27 So. 3d at 77; Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 822 (Fla. Ct. App. 1981). The doctrine is based on the premise that the intermediary, due to his or her expertise and knowledge, is in the best position to evaluate the risks and benefits of the product for that particular patient and to convey appropriate warnings to her. Cates, 73 F.4th at 1350; Mason, 27 So. 3d at 77; Buckner, 400 So. 2d at 822. "The patient is expected to and, it can be presumed, does place primary reliance upon [the physician's judgment, and] [t]he physician decides what facts should be told to the patient." Buckner, 400 So. 2d at 823. "Thus, the duty of a drug manufacturer to warn of the dangers involved in the use of a drug is satisfied if it gives an adequate warning to the physician who prescribes the drug." Mason, 27 So. 3d at 77; accord Cates, 73 F.4th at 1350; Buckner, 400 So. 2d at 823. It therefore follows that if Teva adequately warned Dr. Chlouber of the risk of Paragard breakage, it is entitled to summary judgment of the warnings-based claims.

2. Adequacy of Label

The Court next considers whether, as Teva contends, the Paragard label was adequate as a matter of law. Whether a warning is legally adequate is based on the perspective of the " 'reasonable person' or, here, the reasonable medical

provider." Cates, 73 F.4th at 1350. To fulfill the duty to warn, the manufacturer must provide warnings that are "accurate, clear, and unambiguous," Upjohn Co. v. MacMurdo, 562 So. 2d 680, 681-82 (Fla. 1990), fully apprising the physician of the drug's proper use and potential dangers, Mason, 27 So. 3d at 77. If the warning meets these criteria, the manufacturer is deemed to have satisfied its duty, and the adequacy of the warning may be determined as a matter of law. MacMurdo, 562 So. 2d at 681-82; Mason, 27 So. 3d at 77. If the warning is challenged as insufficient, the issue typically becomes a question of fact for the jury to decide, unless the warning is so clear and unambiguous that reasonable minds could not differ on its adequacy. MacMurdo, 562 So. 2d at 681-82; Mason, 27 So. 3d at 77; Adams v. G.D. Searle & Co., 576 So. 2d 728, 731 (Fla. Ct. App. 1991).

In the 2011 version of the Paragard label, which was the version in use at the time Plaintiff had her Paragard inserted, the Warnings section addressed risk of intrauterine pregnancy, ectopic pregnancy, pelvic infection, immunocompromise, perforation, expulsion, and Wilson's disease. It also warned of embedment, cautioning that "[p]artial penetration or embedment of ParaGard® in the myometrium can make removal difficult. In some cases, surgical removal may be necessary." Dkt. No. [86-9] at 2. In the Adverse Reactions section, the label listed intrauterine pregnancy, septic abortion, ectopic pregnancy, pelvic infection, perforation, and embedment as the most serious

adverse events associated with intrauterine contraception; listed pregnancy, expulsion, and bleeding/pain as events that had caused discontinuation of clinical studies; and stated that anemia, backache, dysmenorrhea, dyspareunia, complete or partial expulsion, leukorrhea, prolonged menstrual flow, menstrual spotting, pain, cramping, urticarial allergic skin reaction, and vaginitis were other adverse events that had been observed. Id.

It was only further down in the Paragard label that breakage was mentioned: in the Continuing Care section, the label stated,

> **If you cannot find the threads in the vagina, check that ParaGard® is still in the uterus.** The threads can retract into the uterus or break, or ParaGard® can break, perforate the uterus, or be expelled. Gentle probing of the cavity, radiography, or sonography may be required to locate the IUD.
>
> If there is evidence of partial expulsion, perforation, or breakage, remove ParaGard®.

Id. at 3 (emphasis in original). In instructions in that section regarding removal of the Paragard, the label further stated,

> Remove ParaGard® with forceps, pulling gently on the exposed threads. The arms of the ParaGard® will fold upwards as it is withdrawn from the uterus. You may immediately insert a new ParaGard® if the patient requests it and has no contraindications.
>
> Embedment or breakage of ParaGard® in the myometrium can make removal difficult. Analgesia, paracervical anesthesia, and cervical dilation may assist in removing an embedded ParaGard. An alligator forceps or other grasping instrument may be helpful. Hysteroscopy may also be helpful.

Id.

The Court finds that there is a genuine issue of material fact as to the adequacy of the warnings in the label. There was no mention of breakage or related injuries in the Warnings or Adverse Reactions sections of the 2011 label. Dkt. No. [100-1] ¶ 50; see also Dkt. No. [86-9] at 2. Dr. Chlouber testified that when he refers to the drug label to learn about the risks of a product like Paragard, he "go[es] to two places, contraindications or the warnings section." Deposition of Richard Chlouber, M.D. ("Chlouber Dep.") at 78-79. Even Defendant's expert readily recognizes that breakage is a clinically significant adverse reaction; that there is a causal relationship between the Paragard and Paragard breakage; and that it is appropriate to put breakage in the warnings section of the Paragard label. Deposition of Jonathan P. Jarow, M.D. ("Jarow Dep."), at 140, 146-49, 159-61, 163, 172. Additionally, there is evidence that there were breakage risks of a different type—without embedment—and of a greater frequency than reflected in the 2011 label, including a 2015 FDA submission created by Teva Head of Pharmacovigilance, Dr. Siyu Liu; the accumulation of miscoded breakage-related adverse event reports over time; and expert witness testimony that Paragard breaks are a common occurrence and that most breakage cases do not occur because of embedment. Dkt. No. [92-1] ¶¶ 25-31, 36-38, 44-47; Dkt. No. [59-13] at 11-12; Dkt. No. [59-16] at 5, 11; Dkt. No. [86-29] at 12, 29; Dkt. No. [89-3] at 127; Dkt. No. [100-1] ¶¶ 70-72, 74, 80, 83-86, 89. It is also notable that by 2024, the Dosage and Administration section at the

beginning of the Paragard label stated that "Paragard can break" and acknowledged that breakage could occur within the first month of placement, Dkt. No. [52-10] at 13, and "device breakage" appeared among the reported Adverse Events, id. at 19. Thus, the Court concludes that a reasonable jury could find that the 2011 label did not provide accurate, clear, and unambiguous warnings of the risk of Paragard breakage.

Defendant therefore is not entitled to summary judgment of the failure-to-warn claims on grounds that the label was adequate as a matter of law.

3. Proximate Cause

Even where a label is insufficient, the learned-intermediary doctrine may still bar a failure-to-warn claim "where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided." Small v. Amgen, Inc., 723 F. App'x 722, 725 (11th Cir. 2018) (cleaned up); accord Cates, 73 F.4th at 1350; Mason, 27 So. 3d at 77. In such cases, "the causal link is broken and the plaintiff cannot recover." Small, 723 F. App'x at 725; accord Cates, 73 F.4th at 1350.

Viewing Dr. Chlouber's testimony in the light most favorable to Plaintiff, as required on summary judgment, the Court concludes that there is a genuine issue of material fact as to whether Dr. Chlouber had actual knowledge of the substance of the breakage warnings Plaintiff advocates and that he would have

taken the same course of action had he received them. First, there is evidence that Dr. Chlouber relied on the Paragard labeling for warnings: he testified that although he could not recall whether he read the Paragard label immediately prior to placing Plaintiff's Paragard, he read the label periodically and would counsel patients on Paragard's labeled warnings and adverse reactions. Dkt. No. [100-1] ¶¶ 14, 15, 18, 54. And although Dr. Chlouber testified that he was aware since residency of the risk that an IUD could break upon removal and cause the patient to need surgery, he also made clear that he believed that the risk was exceedingly low and that he associated breakage exclusively with embedment. Dkt. No. [100-1] ¶¶ 19-22; Clouber Dep. at 37, 89-90. Dr. Chlouber also testified that if he learned that adverse events happened more often or with greater severity than he originally believed, he would reevaluate his risk/benefit analysis or the warnings he would discuss with the patient. Dkt. No. [100-1] ¶¶ 23-25. As discussed in the section immediately above, there is evidence that Paragards broke more often than previously known and even without embedment. Thus, a reasonable jury could conclude that Dr. Chlouber did not have actual knowledge of the true risk of breakage and would have taken a different course of action had he received proper warnings.

B. Fraud

Teva concedes that under Florida law, a fraud claim is an independent cause of action, separate from a failure-to-warn claim. Dkt. No. [100] at 26. In

Florida, fraud has four elements: "(1) a false statement concerning a material fact; (2) the representor's knowledge that the representation is false; (3) an intention that the representation induce another to act on it; and (4) consequent injury by the party acting in reliance on the representation." Butler v. Yusem, 44 So. 3d 102, 105 (Fla. 2010) (internal quotation marks omitted). "[K]nowing concealment or nondisclosure of a material fact may also support an action for fraud . . . where a party in an arm's length transaction undertakes to disclose information" yet fails to disclose all material facts. Gutter v. Wunker, 631 So. 2d 1117, 1118-19 (Fla. Ct. App. 1994); accord In re Takata Airbag Prods. Liab. Litig., No. 14-24009-CV, 2017 WL 775811, at *4 (S.D. Fla. Feb. 27, 2017) ("Florida law imposes a duty to disclose on a defendant if that defendant's failure to speak would render the defendant's own prior speech misleading or deceptive." (cleaned up)).

Teva argues that claims arising from alleged misrepresentations to Dr. Chlouber are subject to summary judgment because the label supplied adequate warning to Dr. Chlouber and because Dr. Chlouber did not rely on the product label when prescribing the Paragard to Plaintiff. Teva further contends that, to the extent Plaintiff's claims for fraud are based on a misrepresentation made directly to her, they fail because her allegations of misrepresentation are vague. Dkt. No. [50] at 35-38; Dkt. No. [100] at 26-28.

As discussed above, the Court finds that Plaintiff has established a genuine issue of material fact as to whether Dr. Chlouber relied on the product label and whether the label contained adequate warnings to enable Dr. Chlouber to appreciate the true risks of Paragard breakage. See supra Part III.A. Under Florida law, a plaintiff adequately alleges a claim for fraud if she can establish that the defendant had misrepresented or omitted material facts about the product in question to the physician, which induced the physician and patient to rely on such misrepresentations or omissions to the patient's detriment. Adams v. G.D. Searle & Co., 576 So.2d 728, 730 (Fla. Ct. App. 1991); Geery v. Ethicon, Inc., Case No. 6:20-cv-1975, 2021 WL 2580167, at *2 (M.D. Fla. Apr. 20, 2021). Consequently, the Court is not persuaded that summary judgment is warranted on the claims of fraud arising from representations made or information withheld from Dr. Chlouber.

However, the Court is persuaded that Plaintiff has failed to present evidence sufficient to enable a reasonable jury to determine that Teva made a misrepresentation directly to her. To survive summary judgment, a plaintiff alleging fraud must describe the misrepresentation with a high level of specificity. Houri v. Boaziz, 196 So. 3d 383, 393 (Fla. Ct. App. 2016) ("Fraud must be pled with particularity and must not only specifically identify a misrepresentation of fact but also identify when, where, or the manner in which it was made."). Plaintiff states in her briefing and statement of material fact simply that she "did

a Google search and read online about Paragard," "clicked the site for Paragard," and "chose Paragard based on representations made directly to her via the Paragard website." Dkt. No. [88] at 55 (citing Pl. Dep. at 51:4-8, 133:4-19, 172:8-18, 174:14-19); Dkt. No. [100-1] ¶ 2 (citing Pl. Dep. at 51:4-23, 131:6-8). Even if these representations were enough to support a fraud claim, they are not supported by the cited evidence, which discusses Plaintiff's online research in general but does not in fact identify any specific misrepresentations made to Plaintiff by Teva on the Paragard website:

> Q. Okay. Have you ever gone to a Teva website and looked at anything with respect to ParaGard?
>
> A. Prior to insertion, I did research on different types of birth control, different types of IUD, so I did a Google search and read online about ParaGard.
>
> Q. Okay. And since your insertion was in 2012, this would have been sometime in 2011/2012 prior to the insertion?
>
> A. Yes.
>
> . . .
>
> Q. So the Google searches or information you looked at, you don't recall one way or the other if it was with respect to Teva or Cooper, just that it was about ParaGard?
>
> A. I did -- my Google search was for specifically ParaGard and I clicked the site for ParaGard.

Pl. Dep. at 51:4-24.

> A. I did research of different types of birth control online as well as asked the nurse practitioner at the gynecologist's office.

Pl. Dep. at 131:6-8.

Q. How did you learn -- you mentioned you weighed the risks and benefits; right? I think you testified to that.

A. Yes.

Q. How did you learn about the risks and benefits of ParaGard?

A. I reviewed online information about ParaGard and compared it to other options.

Q. What did you understand the risks of ParaGard to be?

A. I understood that there was a risk of still being able to be pregnant while having the IUD. And that's the biggest risk I remember.

Q. You said that's the biggest risk. Do you remember any other risks?

A. No.

Pl. Dep. at 133:4-19.[3]

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[3] The remainder of the cited testimony does not refer to Plaintiff's research at all:

Q. If the nurse practitioner or Dr. Chlouber had told you that surgery may sometimes be needed to remove the ParaGard, would you have agreed to have the ParaGard placed in 2012?

A. No.

Q. If Dr. Chlouber or the nurse practitioner had told you that difficult removal is a risk of use of ParaGard, would you have agreed to have the ParaGard placed in 2012?

A. No, I would not.

Pl. Dep. at 172:8-18 (objection omitted).

Q. If you had been told that expulsion is a risk of ParaGard, would you have agreed to have the ParaGard placed?

Thus, while the Court is not persuaded by Teva's argument for summary judgment of the claims arising from fraudulent misrepresentations made to Dr. Chlouber or information fraudulently withheld from him, it is persuaded that Plaintiff has failed to set forth evidence that would enable a reasonable jury to determine that Teva made fraudulent representations to her.

C. Breach of Warranty

Defendant additionally contends that it is entitled to summary judgment of the breach-of-warranty claims because Plaintiff was required to—and failed to—provide it with notice of the alleged breach prior to filing suit. Dkt. No. [50] at 39. Plaintiff does not argue that she provided notice and instead contends that she was not required to do so. Dkt. No. [88] at 59.

Section 672.607 of the Florida code provides that "where a tender has been accepted, . . . [t]he buyer must within a reasonable time after he or she discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." Fla. Stat. § 672.607(3)(a). According to Plaintiff, she purchased her Paragard from Defendant. Dkt. No. [100-1] ¶ 8. Thus, Plaintiff was the buyer, Defendant was the seller, and Plaintiff therefore was required to provide notice of breach prior to filing suit. See, e.g., Fed. Ins. Co. v. Lazzara

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A. No. Yes, I would have, because I felt it was safe.
Pl. Dep. at 174:14-19 (objection omitted).

Yachts of N. Am., Inc., No. 8:09-CV-607-T-27MAP, 2010 WL 1223126, at *5 (M.D. Fla. Mar. 25, 2010) ("[N]otice to the manufacturer has been required where the evidence demonstrates that the manufacturer was not remote but was 'in effect a direct seller to the plaintiff[].' "); Fineman v. Ferragamo USA Inc., 672 F. Supp. 3d 1302, 1307 (S.D. Fla. 2023) (explaining that the notice requirement protects the seller's right to inspect goods); Gen. Matters, Inc. v. Paramount Canning Co., 382 So. 2d 1262, 1264 (Fla. Ct. App. 1980) (same).

Plaintiff has not shown evidence that she provided notice to Defendant of her breach-of-warranty claims prior to filing suit. Defendant is thus entitled to summary judgment of the claims.

D. Design-Defect Claims

To assert a claim for design defect under Florida law, the plaintiff must prove "first, that the product is defective; and second, that such defect caused [her] injuries." Cates, 73 F.4th at 1350-51 (cleaned up). To prove a design defect, a plaintiff may offer evidence under the consumer-expectations test or the risk-utility test. Aubin v. Union Carbide Corp., 177 So. 3d 489, 511-12 (Fla. 2015).

Plaintiff proceeds under the consumer-expectations test. Dkt. No. [88] at 44-46. "The consumer expectations test . . . 'considers whether a product is unreasonably dangerous because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.' " Cates, 73 F.4th at 1351 (quoting Aubin, 177 So. 3d at 503). "Even so, 'a

manufacturer is not under a duty in strict liability to design a product which is totally incapable of injuring' consumers." Cates, 73 F.4th at 1352-53 (quoting Grieco v. Daiho Sangyo, Inc., 344 So. 3d 11, 19 (Fla. Ct. App. 2022)). "Whether a product is 'unreasonabl[y] dangerous' is 'based on an objective standard and not the viewpoint of any particular customer.' " Cates, 73 F.4th at 1352-53 (quoting Liggett Grp., Inc. v. Davis, 973 So. 2d 467, 475 (Fla. Ct. App. 2007)).

Teva argues that the design defect claims still pending in this case fail because Plaintiff lacks admissible expert testimony establishing that her Paragard more likely than not broke because of a design defect in the product. The Court does not agree.

It first bears noting that expert testimony is not always necessary where a defect is obvious. Dugas v. 3M Co., Case No. 3:14-cv-1096, 2016 WL 3966142, at *4 (M.D. Fla. June 30, 2016) (citing Humphreys v. Gen. Motors Corp., 839 F. Supp. 822, 826 (N.D. Fla. 1993)). In this case, there is no question that the Paragard caused Plaintiff's injury: the device broke, and Plaintiff had to have surgery, under anesthesia, to have fragments removed.

Viewed together in the light most favorable to Plaintiff, Plaintiff's evidence is also sufficient to enable a reasonable jury to determine that it was a design defect that caused Plaintiff's Paragard to break. Plaintiff's testimony and the testimony of her treating physicians, Dr. Chlouber and Dr. Kero, establish that the Paragard was used in its intended manner: that it was prescribed and placed

by an experienced healthcare provider, that it was checked after four weeks, as recommended, and that Plaintiff sought to have it removed by an experienced physician before the recommended 10 years had elapsed. Plaintiff's and Dr. Kero's testimony also establishes a genuine issue of material fact as to whether Plaintiff's Paragard failed to perform as safely as an ordinary consumer would expect when used as intended and that it caused her injuries, as both Plaintiff and Dr. Kero testified that the Paragard broke at removal, that one arm of the T-shaped Paragard frame remained inside of Plaintiff, and that Plaintiff had to have surgery to have the fragment removed, and Plaintiff testified that Dr. Kero seemed upset that the Paragard was broken at removal and said that it should not have happened. Again, even Defendant's expert recognizes that breakage is a clinically significant adverse reaction. Jarow Dep. at 146. Plaintiff also proffered evidence that would enable a reasonable jury to attribute the breakage to a design defect: Dr. Kero testified that she did not encounter resistance during the first attempt at removal, which indicates lack of embedment as a reason for the breakage; Dr. Liu observed that multiple after-market reports of Paragard breakage indicated that Paragard was prone to break without embedment; and Plaintiff's materials expert, Jimmy Mays, Ph.D., testified that the polyethylene used in the T-shaped Paragard frame after around the year 2007 had a propensity to break down in the body, that the change in materials led to more breakages, and that the high levels of barium sulfate used in the Paragard

frame also contributes to its propensity to break. Consequently, the Court concludes that Plaintiff has established a genuine issue of material fact as to her design-defect claims.

E. Gross Negligence and Punitive Damages

The parties disagree over whether Plaintiff's claims for punitive damages are subject to Florida law or New York law. In response to an interrogatory, however, Plaintiff stated that she is entitled to punitive damages under Florida Statute § 768.72. Dkt. No. [50-10] at 15. Plaintiff argues that she should not be held to the statement because it appeared in an unverified interrogatory response and because Plaintiff objected to the interrogatory as not within her personal knowledge and to the extent it sought a legal conclusion. The Court does not agree. Plaintiff was asked in the interrogatory only whether she contended that she was entitled to punitive damages and, if so, to identify the conduct underlying the claim and any documents supporting the contention. Id. The interrogatory did not ask for legal grounds for the claim, and Plaintiff will not be permitted to rescind the voluntary concession made under the signature of her attorney. Plaintiff's claims for punitive damages will therefore be evaluated under Florida law.

Punitive damages are a certain type of damages awarded in civil cases to punish a defendant for egregious misconduct and to deter similar conduct in the future. BDO Seidman, LLP v. Banco Espirito Santo Int'l, 38 So. 3d 874, 876

(Fla. Ct. App. 2010). Under Florida law, gross negligence is not a standalone claim. Instead, gross negligence is a standard of conduct that may serve as a predicate to a claim for punitive damages. Smith v. Ethicon, Inc., Case No. 4:20-cv-394, 2020 WL 9071685, at *3 (N.D. Fla. Dec. 28, 2020) (citing Johns-Manville Sales Corp. v. Janssens, 463 So. 2d 242, 247 (Fla. Ct. App. 1984)).

Under Florida law, "[a] defendant may be held liable for punitive damages only if the trier of fact, based on clear and convincing evidence, finds that the defendant was personally guilty of intentional misconduct or gross negligence." Fla. Stat. § 768.72(2). In this context, "intentional misconduct" means that the defendant "had actual knowledge of the wrongfulness of the conduct and the high probability that injury or damage to the claimant would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage." Id. § 768.72(2)(a). "Gross negligence" is defined as conduct that was "so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct." Fla. Stat. § 768.72(2)(b).

Once again viewing the evidence and all reasonable inferences that may be drawn therefrom in the light most favorable to Plaintiff, the Court finds that Plaintiff has supplied a basis upon which a reasonable finder of fact could conclude that Defendant was grossly negligent and that Plaintiff should therefore be awarded punitive damages. In an email dated March 16, 2010, a Teva auditor

noted that investigation into the root cause of Paragard complaints was "pretty sparse," that reports were being miscoded as "inconclusive/minor," and that employees who should be investigating were not following work instructions or opening emails. Dkt. No. [86-49] at 2. He also suggested that it might be that those charged with investigating adverse events might not be able to keep up with the volume. Id. A pharmacovigilance audit undertaken in early 2011 documented 12 "critical" findings. Dkt. No. [86-42] at 3. "The basic message [from the audit was] that nearly all the systems are out of control and the complete reporting of [adverse events] and the full compliance [with] worldwide regulatory requirements cannot be ensured." Id. The auditor called it a "very serious situation" and recommended that remediation begin immediately. Id. at 4. An assessment prepared in anticipation of a February 2012 audit observed that although there was an increase in complaints of component breakage occurring in 2010 and 2011, records did not contain "detailed discussion of the complaint increase in the summary sections of 2010 and 2011 or Management Review as to the investigation, possible causes and remediation activities" and that "the component breakage issue was discussed as a one time point aberration." Dkt. No. [86-43] at 3. Plaintiff's materials expert proffers an opinion that ongoing product testing was inadequate. Dkt. No. [56-5] at 64-69. The FDA also noted a lack of robust testing on the limits of the product design. Dkt. No. [52-8] at 15. In 2015, after reviewing historical adverse event data going back to the launch of

Paragard, Dr. Liu quickly identified that device breakage qualified as a reportable adverse event and was not already adequately discussed and included under Warnings, Precautions, and Adverse Reactions sections of the product label. Dkt. No. [59-16] at 5; Dkt. No. [92-1] ¶¶ 27, 28, 30. When asked at his deposition why Teva had not made the label-change recommendation earlier, Dr. Liu concluded that Teva had assumed the label it had acquired from the prior NDA holder had been adequate, which suggests that he believed that Teva should have updated the Paragard label years earlier to provide breakage warnings. Dkt. No. [92-1] ¶ 29. Later analysis also showed that historical coding inconsistencies obscured the magnitude of the breakage reports. Dkt. No. [92-1] ¶¶ 36-38, 44-47.

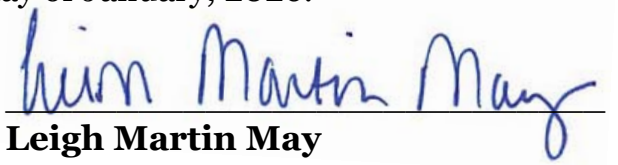
The Eleventh Circuit has upheld punitive damages under Florida law on similar facts. See Taylor v. Mentor Worldwide LLC, 940 F.3d 582, 598 (11th Cir. 2019) (holding that the record was sufficient to authorize punitive damages under Florida law where it contained evidence that the defendant did not conduct sufficient product testing, "including tests as to degradation despite it being well known that heat and pressure cause polypropylene to degrade"; knew of the relatively high rate of complications associated with its product but concealed or materially understated the risks; and ignored warnings from employees and physicians outside the company). Consequently, the Court finds sufficient evidence for the punitive damages claim to go forward to trial.

In sum, the Court concludes that the putative claim for gross negligence is due to be dismissed but that the claim for punitive damages is sufficient to go to a jury.

IV. CONCLUSION

In accordance with the foregoing, Teva's motion for summary judgment, Dkt. No. [50], is **GRANTED IN PART AND DENIED IN PART**. The motion is **GRANTED** as to the fraud claims arising from misrepresentations allegedly made directly to Plaintiff, as to the breach-of-warranty claims, and as to the claim for gross negligence, and **DENIED** as to all other remaining claims.

IT IS SO ORDERED this 5th day of January, 2026.



Leigh Martin May
Chief United States District Judge